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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,365	08/28/2003	Guangwen Wei	#792-A-PCT-US	7677

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EXAMINER	
HISSONG, BRUCE D	
ART UNIT	**PAPER NUMBER**
1646	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/650,365	WEI ET AL.	
	Examiner	Art Unit	
	Bruce D. Hissong, Ph.D.	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *48-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *48-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/20/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

1. The Applicant's response to the office action mailed on 9/20/2006, including arguments/remarks and amended claims, was received on 12/20/2006, and has been entered into the record.

2. The Applicant has cancelled claims 38-47, and added new claims 48-62, which are now pending and are the subject of this office action.

Information Disclosure Statement

The information disclosure statement received on 12/20/2006 has been fully considered by the Examiner.

Claim Objections

1. The Examiner suggests the syntax of claim 55 can be improved by amending the claim to read "adjusted according to the codon preference".

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. Claim 57 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). See rejection #6 under 35 U.S.C. 112, 2nd paragraph, below.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 56-59 are rejected under 35 USC § 112, second paragraph, as being indefinite regarding the phrase "super-compound interferon", as applied to claims 29-37 on page 3 of the office action mailed on 9/20/2006.

2. Claims 48-62 are rejected under 35 USC § 112, second paragraph, as being indefinite regarding the phrase "changed spatial configuration and enhanced biological activity", as applied to claim 38 on pages 3-4 of the office action mailed on 9/20/2006. In the response received on 12/20/2006, the Applicant argues that claim 48 has now been amended to recite an interferon that has different spatial configuration and enhanced biological activity as compared to an interferon not encoded by nucleotide sequence SEQ ID NO: 1 or 3, and therefore the claim is definite regarding differences in spatial configuration.

This argument has been fully considered and is not persuasive. Although the claims now include the limitation of a recombinant interferon having different spatial configuration and enhanced biological activity relative to an interferon encoded by SEQ ID NO: 1 or 3, the claims do not describe the metes and bounds of the term "different", which could encompass any change, to any degree, of the physical configuration of an interferon polypeptide. Therefore, because the metes and bounds of "different spatial configuration" are not defined, the claims are indefinite. Claims 49-62 are rejected for depending from rejected claim 48.

3. Claims 53-54 are rejected under 35 USC § 112, second paragraph, as being indefinite regarding the phrase "special promoter", as applied to claim 41 on page 4 of the office action mailed on 9/20/2006.

4. Claims 57-59 recite the limitation "the super-compound interferon". There is insufficient antecedent basis for this limitation in the claims.

5. Claim 57 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is drawn to a recombinant interferon used in a "particular concentration". It is not clear from the claim what a "particular" concentration would be, and thus the claim is indefinite.

6. Claim 57 provides for the use of the super-compound interferon, but the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

7. Claim 57 recites the limitation "the high efficacy". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 112, first paragraph – written description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Rejection of claims 38-47 under 35 USC § 112, first paragraph, for failing to comply with the written description requirement, as set forth on pages 4-6 of the office action mailed on 9/20/2006, is moot in response to Applicant's cancellation of the claims, and the amendments to new claims 48-62 to specifically recite a recombinant interferon polypeptide having the sequence of SEQ ID NO: 2 or 4, and encoded by the nucleic acid sequence of SEQ ID NO: 1 or 3.

2. Claims 48-62 are rejected under 35 USC § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

claimed invention. **This is a new matter rejection.** In the amendments received on 12/20/2006, the Applicant has amended the claims to read on a recombinant interferon having the an amino acid sequence of SEQ ID NO: 2 or 4, and encoded by the polynucleotide sequences of SEQ ID NO: 1 or 3, wherein said interferon has different spatial configuration and enhanced biological activity as compared to an interferon that is not encoded by the nucleotide sequences of SEQ ID NO: 1 or 3. The specification does teach a recombinant interferon that is different from Infergen® as determined by circular dichroism. However, the specification does not specifically recite a recombinant interferon encoded by SEQ ID NO: 1 or 3 and having the amino acid sequence of SEQ ID NO: 2 or 4, and further having different spatial configuration and enhanced biological activity as compared to an interferon polypeptide that is not encoded by SEQ ID NO: 1 or 3.

Claim Rejections - 35 USC § 112, first paragraph - enablement

Claims 52-62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

New claim 52 is drawn to a host cell comprising a polynucleotide comprising SEQ ID NO: 1 or 3. As written, the breadth of the claim is excessive because it encompasses virtually any cell type in any location. Because the host cell of claim 52 could conceivably be any cell within a living organism, the claim can be interpreted as reading on a method of gene therapy. There is no guidance or examples in the specification that would teach a person of ordinary skill in the art how to use the polynucleotides of SEQ ID NO: 1 or 3 in any type of gene therapy. One of ordinary skill in the art would not be able to predict which patient populations would benefit from such therapy, and which cell types should be targeted, or how to specifically target the polynucleotides of SEQ ID NO: 1 or 3 to these cell types. Therefore, one of ordinary skill in the art would require further, undue experimentation in order to make and use an interferon encoded by the polynucleotides of SEQ ID NO: 1 or 3 in all possible host cells. This rejection can be obviated by amending the claim to read "an *isolated* host cell.....". Claims 53-62 are rejected for depending from rejected claim 52.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 48-49, 52-53, and 55-60 are rejected under 35 USC § 102(b) as being anticipated by Stabinsky *et al* (US 4,695,623), or Stabinsky *et al* (US 4,897,471), or Alton *et al* (EP422697A), as applied to claims 38-40 and 44-46 on pages 6-7 of the office action mailed on 9/20/2006. The claims of the instant invention are drawn to a recombinant interferon encoded by a polynucleotide having a sequence of SEQ ID NO: 1 or 3, and having an amino acid sequence of SEQ ID NO: 2 or 4, and furthermore having different spatial configuration and enhanced biological activity as compared to an interferon having an amino acid sequence of SEQ ID NO: 2 or 4 but not encoded by SEQ ID NO: 1 or 3. The claims are further drawn to pharmaceutical compositions of said recombinant interferon, and said recombinant interferon produced by expression in an appropriate host cell.

In the response received on 12/20/2006, the Applicant argues that although the recombinant interferon of the instant invention has the same amino acid sequence as that of consensus interferon, the recombinant interferon of the instant invention is encoded by the nucleic acids of SEQ ID NO: 1 or 3. Furthermore, the Applicant argues that the instant specification teaches that the recombinant interferon of the instant invention has a different spatial configuration and enhanced biological activity compared to the interferon of the art, and therefore, neither the '623 patent, '471 patent, nor the '697 application meet the limitations of the claims of the instant invention.

These arguments have been fully considered and are not persuasive. Although the instant claims recite a recombinant interferon encoded by SEQ ID NO: 1 or 3, it is noted that the claims of the instant invention claim a *product*, namely a recombinant interferon having the amino acid sequence of SEQ ID NO: 2 or 4, rather than a process of preparing that product. Thus, because the product (recombinant interferon of SEQ ID NO: 2 or 4) is what is actually being claimed, the disclosure of the '623 patent, '471 patent, or '697 application, which all teach a polypeptide having the sequence of SEQ ID NO: 2 or 4, meet the limitations of claim 48. Furthermore, the '623 patent teaches expressing consensus interferon-α with an expression

system (column 3, lines 21-35), and vectors comprising interferon-α genes that have been artificially synthesized and adjusted for prokaryotic codon preference (column 4, lines 29-50; column 6, line 41 – column 7, line 35; column 11, line 44 – column 12, line 65). Thus, the '623 patent teaches artificial genes encoding super-compound IFN (consensus IFN-α), vectors and an expression system for super-compound IFN, and appropriate host cells for expression (E. coli – see column 39, lines 27-44). The '623 patent also teaches methods of producing recombinant consensus IFN polypeptides by transforming E. coli with a vector encoding IFN polypeptides, wherein said vector comprises an artificial gene that is optimized for E. coli codon preference and encodes an IFN polypeptide, culturing said E. coli under specific conditions favoring growth of the bacteria, and harvesting said IFN polypeptides from E. coli lysates (column 25, lines 16-29). Therefore the disclosure of the '623 patent meets the limitations of claims 48, 52-53, and 55-60 of the instant application. Furthermore, although the '623 does not specifically recite an interferon capable of directly inhibiting DNA duplication and secretion of HBsAg and HBeAg of the hepatitis B virus, it is noted that the interferon of the '623 patent would inherently possess the ability to inhibit DNA duplication and secretion of HBsAg and HBeAg of hepatitis B virus. Therefore the process taught by the '623 patent, in absence of evidence to the contrary, would be expected to inherently produce a super-compound IFN that maintains high efficacy (Ex parte Novitski, 26 USPQ 1391), thus meeting the limitations of claim 49 of the instant application.

2. Claims 48-51 are rejected under 35 USC § 102(b) as being anticipated by Blatt *et al* (US 5,372,808), as applied to claims 38 and 44-47 on pages 7-8 of the office action mailed on 9/20/2006. The subject matter of the claims of the instant invention is discussed *supra*. Claims 50-51 are further drawn to a pharmaceutical composition of the recombinant interferon of claim 48.

In the response received on 12/20/2006, the Applicant argues that although the recombinant interferon of the instant invention has the same amino acid sequence as that of consensus interferon, the recombinant interferon of the instant invention is encoded by the nucleic acids of SEQ ID NO: 1 or 3. Furthermore, the Applicant argues that the instant specification teaches that the recombinant interferon of the instant invention has a different spatial configuration and enhanced biological activity compared to the interferon of the art, and therefore, the '808 patent does not meet the limitations of the claims of the instant invention.

These arguments have been fully considered and are not persuasive. Although the instant claims recite a recombinant interferon encoded by SEQ ID NO: 1 or 3, it is noted that the claims of the instant invention claim a *product*, namely a recombinant interferon having the amino acid sequence of SEQ ID NO: 2 or 4, rather than a process of preparing that product. Thus, because the product (recombinant interferon of SEQ ID NO: 2 or 4) is what is actually being claimed, the disclosure of the '808 patent, which teaches a polypeptide having the sequence of SEQ ID NO: 2 or 4, meet the limitations of claim 48. Furthermore, the interferon of the '808 patent would inherently possess the ability to inhibit DNA duplication and secretion of HBsAg and HBeAg of hepatitis B virus. Therefore the process taught by the '623 patent, in absence of evidence to the contrary, would be expected to inherently produce a super-compound IFN that maintains high efficacy (Ex parte Novitski, 26 USPQ 1391), thus meeting the limitations of claim 49 of the instant application. Finally, because the '808 patent teaches pharmaceutical compositions comprising the recombinant interferon having the same amino acid sequence as that of the instant application, the disclosure of the '808 patent meets the limitations of claim 50-51.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 48-62 are rejected under 35 USC § 103(a) as being obvious in view of the combination of Stabinsky *et al* (US 4,695,623), or Stabinsky *et al* (US 4,897,471), or Alton *et al* (EP422697A), in view of Nasoff *et al*, as applied to claims 38-46 on pages 8-9 of the office action mailed on 9/20/2006. The subject matter of the claims of the instant invention is discussed *supra*. Claims 53-54 further recite a recombinant interferon expressed with a special promoter, and specifically, the pBad promoter.

In the response received on 12/20/2006, the Applicant argues that although the recombinant interferon of the instant invention has the same amino acid sequence as that of consensus interferon, the recombinant interferon of the instant invention is encoded by the

nucleic acids of SEQ ID NO: 1 or 3. Furthermore, the Applicant argues that the instant specification teaches that the recombinant interferon of the instant invention has a different spatial configuration and enhanced biological activity compared to the interferon of the art, and therefore the claims of the instant invention cannot be obvious in view of any combination based on the '623 patent, the '471 patent, or the '687 application.

These arguments have been fully considered and are not persuasive. As stated above in the rejection under 35 U.S.C. 102(b), the disclosures of the '623 or '471 patents, or the '697 application, meet the limitations of claims 48 and 52 of the instant application. As set forth in the previous office action mailed on 9/20/2006, Nasoff *et al* teaches expression of proteins using the pBad promoter. Thus, as set forth in the previous office action, it would have been obvious to one of ordinary skill in the art to express the interferon of the '623 patent, '471 patent, or the '697 application using an expression system which utilizes the pBad promoter. Furthermore, although the '623 patent, '471 patent, and the '697 application do not explicitly teach pharmaceutical compositions of recombinant interferons, such compositions are well-known in the art and it would be obvious to a skilled artisan to incorporate the interferons of the '623 patent, '471 patent, or the '697 application in a pharmaceutical composition.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 48-62 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of co-pending Application 10/928,956, as applied to claims 38-45 on pages 9-10 of the previous office action mailed on 9/20/2006. In the response received on 12/20/2006, the Applicant has requested that the rejection be held in abeyance until allowable subject matter is identified.

2. Claims 48-62 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 12-17, and 21 of co-pending Application 11/077,813, as applied to claims 38-45 on pages 10-11 of the previous office action mailed on 9/20/2006. In the response received on 12/20/2006, the Applicant has requested that the rejection be held in abeyance until allowable subject matter is identified.

Conclusion

No claim is allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D., whose telephone number is (571) 272-3324. The examiner can normally be reached M-F from 8:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D., can be

reached at (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BDH
Art Unit 1646

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